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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,104	04/24/2001	Fritz Magerl	LUD-PT002-PA1083US	6204

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EXAMINER

CHEVALIER, ALICIA ANN

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 03/26/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

A9-9

Office Action Summary	Application No.	Applicant(s)	
	09/701,104	MAGERL ET AL.	
	Examiner	Art Unit	
	Alicia Chevalier	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 April 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Drawings

1. This applicant does not contain drawings as described in the specification. The drawings are objected to under 37 CFR 1.83(a) because they are missing and fail to show figures 1 and 2 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because they fail to set forth the composition or structure of the reinforcing fibers or fibrous parts and only claim properties of the small percentage of the

reinforcing elements. Claims that merely set forth physical characteristics desired in an article, and not setting forth specific compositions which would meet such characteristics are invalid as vague, indefinite, and functional since they cover any conceivable combination of ingredients either presently existing or which might be discovered in the future. *Ex parte Slob* (PO BdApp) 157 USPQ 172. Essentially claim 1 recites the property “at least a small percentage of the content of reinforcing elements made out of a material whose x-ray absorption is higher than that of the material of the remaining reinforcing elements,” without setting forth the composition or structure of the fibers that creates this property. Claims 3-5, 7, 9, 11, 12, and 14 also recite this limitation regarding the x-ray absorption of the reinforcing elements without setting forth the composition or structure of the reinforcing element that creates this property.

Claim 1 is unclear in scope which renders the claims vague and indefinite. Claim 1 first recites “integrated reinforcing elements in the form of fibers or fibrous parts” and then recites “a small percentage of the content of reinforcing elements made out of a material whose x-ray absorption is higher than that of the material of the remaining reinforcing elements. It is unclear from the claim language if the fibers are all made of the same material or if Applicant is trying to claim at least two different types of reinforcing fibers or two different types of reinforcing elements.

The term “high” in claim 2 is unclear which renders the claim vague and indefinite. It is unclear what percentage of fibers to polymer matrix constitutes a “high fiber content.”

Claim 3 is unclear in scope which renders it vague and indefinite. Claim 3 recites the composite “is prefabricated as a profiled rod material .. and can be or has been molded into a shape required for the final component.” It is unclear from the claim language what shape

Applicant is claiming, any or a rod shape. Furthermore, it is unclear if these limitations are merely method limitations or actual structural limitations.

Claim 5 recites the limitation "fibers made out of a material with higher x-ray absorption" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is believed that claim 5 should really depend from claim 4.

Claim 6 is unclear in scope which renders the claim vague and indefinite. It is unclear is the limitation "the used fibers are enveloped on the surface but eh matrix" is a structural limitation or a method limitation. Furthermore, it is unclear what "the used fibers" are.

Claim 8 is unclear in scope which renders it vague and indefinite. It is unclear if Applicant is claiming any metal or metal oxides with high attenuation coefficients or just the ones listed.

Claim 9 recites the limitation "component" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 upon which claim 9 depends does not recite any limitations directed to "a component."

Claim 9 recites the limitation "a composite" in line 1. There is insufficient antecedent basis for this limitation in the claim. "A" should be "the".

Claim 9 is unclear in scope which renders the claim vague and indefinite. It is unclear what kind of structure the limitations "predictable progression and "predictable quantity and orientation of reinforcing elements" imparts on the composite.

Claim 13 recites the limitation "the connecting element" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 and 14 is indefinite because they fail to set forth the composition or structure of the connecting/component and only claim properties of stiffness in relative term. Claims that merely set forth physical characteristics desired in an article, and not setting forth specific compositions which would meet such characteristics are invalid as vague, indefinite, and functional since they cover any conceivable combination of ingredients either presently existing or which might be discovered in the future. *Ex parte Slob* (PO BdApp) 157 USPQ 172.

Claims 13 and 14 are unclear in scope which render them vague and indefinite. It is unclear the structural limitations produced by the stiffness requirements.

Regarding claim 15, the phrase "e.g. an osteosynthesis plate" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. It is unclear whether the applicant is claiming a component or osteosynthesis plate. See MPEP § 2173.05(d). Furthermore, "an osteosynthesis plate" is insufficient antecedent basis for this limitation ~~to~~ claim 15.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al. (EP 0551574 A1).

Chu discloses a composite implant comprising a carbon and metal fiber reinforced PAEK (poly-aryl-ether-ketone) thermoplastic material. The metal fibers can be stainless steel or titanium alloys. See column 2, lines 16-51. From figure 2 it can be seen that these composite has a rod profile.

Although Chu does not explicitly teach the limitations at least a small percentage of the content of reinforcing elements made out of a material whose x-ray absorption is higher than that of the material of the remaining reinforcing elements, it is reasonable to presume that said limitations are inherent to the invention. Support for said presumption is found in the use of similar materials (i.e. nonmagnetic metal fibers) used to produce the implant. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

The phrase “for the manufacture of ...” is an intended use and it has been held that the recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations.

Process limitations are given little or no patentable weight. The method of forming the product is not germane to the issue of patentability of the product itself. Further, when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claim in a product-by-process claim, the burden is on the Applicant to present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of the prior art. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972); *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974). This burden is NOT

discharged solely because the product was derived from a process not known to the prior art. *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974).

Furthermore, the determination of patentability for a product-by-process claim is based on the product itself and not on the method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 946, 966 (Fed. Cir. 1985) and MPEP §2113.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loher et al. (WO 96/19336) in view of Ellis (GB 2203342 A).

Loher discloses a component mad of round rods comprising a carbon fiber reinforced PAEK (poly-aryl-ether-ketone) thermoplastic material that serve as blanks for screw manufacture of other shapes such as strip shaped, rail-shaped, or plate-shaped (page 10 and 12). The component comprises a fiber volume content of more than 50%, preferably 60% and the fiber orientation can vary between 0 and $\pm 90^\circ$ (page 10). Furthermore, the fibers can be short, long and/or endless (continuous) fibers (page 8).

Loher discloses all the limitations of the instant claimed invention except for fibers made of nonmagnetic metal.

Ellis discloses component for medical implant that comprise a thermoplastic material with metal fibers such as gold, platinum, titanium, palladium and their alloys, and stainless steel (page 3). The metallic material is used to make the component radiologically opaque (abstract).

Although Ellis does not explicitly teach the limitations at least a small percentage of the content of reinforcing elements made out of a material whose x-ray absorption is higher than that of the material of the remaining reinforcing elements, it is reasonable to presume that said limitations are inherent to the invention. Support for said presumption is found in the use of similar materials (i.e. nonmagnetic metal fibers) used to produce the implant. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a small about of metallic fibers as taught by Ellis to the implant component of Loher because the metallic fibers would allow the implant of Loher to be visible on x-ray machines.

The phrase “for the manufacture of ...” is an intended use and it has been held that the recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations.

Process limitations are given little or no patentable weight. The method of forming the product is not germane to the issue of patentability of the product itself. Further, when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claim in a product-by-process claim, the burden is on the Applicant to

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present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of the prior art. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972); *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974). This burden is NOT discharged solely because the product was derived from a process not known to the prior art. *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974).

Furthermore, the determination of patentability for a product-by-process claim is based on the product itself and not on the method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 946, 966 (Fed. Cir. 1985) and MPEP §2113.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Chevalier whose telephone number is (703) 305-1139. The Examiner can normally be reached on Monday through Thursday from 8:00 a.m. to 5:00 p.m. The Examiner can also be reached on alternate Fridays

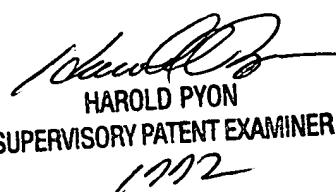
If attempts to reach the Examiner are unsuccessful, the Examiner's supervisor, Harold Pyon can be reached by dialing (703) 308-4251. The fax phone number for the organization official non-final papers is (703) 872-9310. The fax number for after final papers is (703) 872-9311.

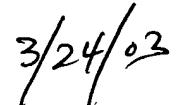
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose phone number is (703) 308-0661.

ac

3/21/03




HAROLD PYON
SUPERVISORY PATENT EXAMINER
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